

**Amendments to the Claims**

This listing of claims will replace all prior versions, and listing, of all claims in the application:

**Listing of Claims:**

1. (Currently amended) A two-part prosthetic spinal nucleus device for replacing a nucleus of a spinal disc and being implanted in an intervertebral space within a natural ~~intact~~ annulus and between natural[[,]] ~~intact~~ end plates attached to adjacent axially spaced upper and lower vertebral bones, the device comprising:

a rigid upper shell having a one-piece body including a smooth outer surface for facing and non-invasively contacting the natural end plate of the upper vertebra for sliding engagement therewith and sized to fit within the natural annulus of the spinal disc;

a rigid lower shell having a one-piece body including a smooth outer ~~lower~~ surface for facing and non-invasively contacting the natural end plate of the lower vertebra for sliding engagement therewith and sized to fit within the natural annulus of the spinal disc;

inner, arcuate bearing surfaces of the one-piece bodies of the upper and lower shells that generally face are in sliding engagement with each other;

~~a bearing interface at at least one of the inner surfaces of one of the shells;~~ and

opposite narrow ends of each of the ~~shells~~ shell bodies and elongate sides of each of the ~~shells~~ shell bodies extending between the narrow ends thereof so that the sides are longer than the narrow ends to allow the shells to be arranged with narrow ends of the ~~shells~~ shell bodies leading the shells as the shells are inserted through an incision smaller than the elongated sides of the ~~shells~~ shell bodies so that the natural annulus retains the shells in the intervertebral space with the smooth outer surfaces of the shell bodies extending continuously without interruption across the entire extent thereof between the ends and sides of the respective shell bodies.

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2. (Cancelled)

3. (Currently amended) The device of claim 1 wherein ~~the shells are separate members~~ shell bodies are configured to be sequentially inserted through the incision in the annulus, and be assembled within the annulus.

4. (Withdrawn) The device of claim 1 further including a spacer member configured to cooperate with at least one shell so that the shells have an unexpanded arrangement relative to each other during insertion thereof within the annulus, and an expanded arrangement after insertion in the annulus.

5-10 (Cancelled)

11. (Withdrawn) The device of claim 1 wherein the bearing interface includes the inner surfaces of both of the shells which comprise:

- a convex surface having a predetermined radius of curvature; and
- a concave surface receiving the convex surface and having a predetermined radius of curvature different from that of the convex surface to provide a stiffness for the polyaxial movement between the upper and lower shells.

12. (Withdrawn) The device of claim 1 wherein the outer surface of the rigid upper shell comprises a convex top surface for contacting the natural end plate of the upper vertebra; and  
the outer surface of the rigid lower shell comprises a convex bottom surface for contacting the natural end plate of the lower vertebra.

13. (Withdrawn) The device of claim 12 wherein at least one of the convex surfaces has a radius of curvature greater than a radius of curvature of the vertebra end plate the at least one convex surface contacts.

14. (Withdrawn) The device of claim 12 wherein at least one of the convex surfaces has a radius of curvature smaller than a radius of curvature of the vertebra end plate the at least one convex surface contacts.

15. (Withdrawn) The device of claim 12 wherein at least one of the convex surfaces has a radius of curvature substantially equal to a radius of curvature of the vertebra end plate the at least one convex surface contacts.

16. (Withdrawn) A method of replacing a nucleus of a spinal disc, the method including:  
providing an implant device including a plurality of components;  
determining a minimum bounded loop size through which each of the components can pass;  
providing an incision in an annulus of the spinal disc such that the incision forms a deformable bounded loop generally sized according to the minimum bound loop size through which each of the components can pass;  
orienting the components for insertion through the incision;  
sequentially inserting the components through the incision; and  
assembling the components to form the device within the annulus.

17. (Withdrawn) The method of claim 16 further including the step of rotating at least one of the components after a leading end of the component is inserted within the annulus.

18. (Withdrawn) A method of replacing a nucleus of a spinal disc, the steps including:

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providing an implant device having a rigid top member, a rigid bottom member, and a spacer member;

assembling the device in a collapsed arrangement with a pre-determined size in a pre-determined direction;

providing an incision in an annulus of the spinal disc such that the incision forms a deformable bounded loop sized according to the pre-determined size such that the device in the collapsed arrangement can pass through the incision;

inserting the device in the collapsed arrangement through the incision; and

expanding the device such that the device has an expanded arrangement with a size greater than the pre-determined size at least in the pre-determined direction.

19. (Withdrawn) The method of claim 18 wherein the step of expanding the device includes moving a portion of the spacer member relative to at least one of the top and bottom members.

20. (Withdrawn) The method of claim 18 wherein the step of expanding the device includes injecting a flowable material into the spacer member to expand the spacer member between the top and bottom members.

21. (Currently Amended) The device of claim 1 wherein at least one of the shells includes a gripping projection integral with the body of the one shell configured to allow a separate tool to grip around the projection for tool insertion of the shells through the annulus incision into the intervertebral space and shifting of the shells therein so that the narrow shell ends are not aligned with an insertion direction of the shells through the incision.

22. (Currently Amended) The device of claim 21 wherein the gripping projection comprises a gripping post[[s]] of the at least one of the upper and lower shells that projects from the one shell toward the other of the upper and lower shells.

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23. (Previously presented) The device of claim 21 wherein the gripping projection includes an arcuate engagement surface for rotating the one shell with the tool, and a generally flat abutment surface for locking the one shell against rotation with the tool.

24. (Currently amended) The device of claim 1 wherein the inner, arcuate bearing surfaces ~~interface comprise~~[[s]] engaging concave and convex bearing ~~surface portions of the inner~~ surfaces of the upper and lower ~~shells~~ shell bodies that bear against each other for substantially the entire arcuate extent thereof without discontinuities in the bearing ~~surfaces~~ surface portions.

25. (Currently amended) The device of claim 24 wherein the ~~inner surfaces further~~ shell bodies include flat surface portions adjacent the concave and convex bearing surfaces ~~surface portions~~.

26. (Currently amended) The device of claim 25 wherein the flat surface portion of one of the shell bodies includes an integral ~~including a~~ gripping post projecting away therefrom ~~from at least one of the flat surface portions of the one of the shells~~.

27. (Currently amended) The device of claim 1 wherein ~~the inner surface of one of the shells~~ shell bodies includes a flat surface portion and the inner bearing surface of the one shell body is a concave surface portion recessed from the flat surface portion, and ~~the inner surface of the other shell body~~ includes a flat surface portion and the inner bearing surface of the other shell body is a dome surface projecting beyond the flat surface portion of the other shell body.

28. (Currently amended) The device of claim 1 wherein the smooth, outer surfaces of the ~~shells~~ shell bodies are flat surfaces.

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29. (Withdrawn) The device of claim 1 wherein the shells are separate members, and a spacer member separate from the shell members with the bearing interface formed between the one inner surface of the one shell and a facing surface of the spacer member in engagement therewith.

30. (Withdrawn) The device of claim 29 wherein the spacer member and the other shell have another bearing interface therebetween including bearing surfaces thereof.

31. (Currently amended) The device of claim 1 wherein the bodies of the rigid upper shell and the rigid lower shell are entirely of a polyetheretherketone (PEEK) material; ~~and the bearing interface is at portions of the inner surfaces of both shells to allow relative shifting therebetween~~ so that the PEEK inner-surface portions bearing surfaces bear and articulate against each other and provide optimized wear resistance and cyclic load bearing capacity upon being implanted in the intervertebral space in the annulus.

32. (Canceled)

33. (Currently amended) An articulating orthopedic load bearing implant comprising multiple articulating load bearing members, the members comprising polyetheretherketone, the articulating members having opposing polyetheretherketone surfaces which are configured to engage and move against each other and smooth outer bearing surfaces that face and non-invasively engage with adjacent hard or connective tissue and extend along the entirety of each load bearing member such that each bearing member is allowed to slide along the adjacent hard or connective tissue.

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34. (Previously presented) The articulating orthopedic load bearing implant of claim 33 wherein the engaging surfaces are configured to allow for relative turning movement therebetween.

35. (Previously presented) The articulating orthopedic load bearing implant of claim 33 wherein the engaging surfaces are configured to allow for relative sliding movement therebetween.

36. (Previously presented) The articulating orthopedic load bearing implant of claim 35 wherein one of the members has a concave polyetheretherketone bearing surface and another one of the members has a convex polyetheretherketone bearing surface in engagement with the concave surface.

37. (Currently amended) The articulating orthopedic load bearing implant of claim 33 wherein the ~~members include outer polyetheretherketone bearing surfaces~~ comprise polyetheretherketone configured to engage and move relative to bone material engaged therewith.

38. (Previously presented) The articulating orthopedic load bearing implant of claim 36 wherein the concave surface and convex surface are configured to permit polyaxial movement of the members relative to each other.

39. (Previously presented) The articulating orthopedic load bearing implant of claim 33 wherein the members cooperate to form a nucleus device for replacing a nucleus of a spinal disc and are sized to fit within and be retained by a natural annulus of the disc.

40. (Previously presented) The articulating orthopedic load bearing implant of claim 37 wherein the members cooperate to form a nucleus device for replacing a nucleus of a spinal disc and are sized to fit within and be retained by a natural annulus of the disc.

41. (Previously presented) The articulating orthopedic load bearing implant of claim 38 wherein the members cooperate to form a nucleus device for replacing a nucleus of a spinal disc and are sized to fit within and be retained by a natural annulus of the disc.

42. (Currently amended) A nucleus implant device for replacing a nucleus of an intervertebral spinal disc leaving the natural spinal annulus and end plates of adjacent upper and lower vertebrae intact, the nucleus implant device comprising:

an upper load bearing member for being implanted in an intervertebral space within the intact, natural annulus adjacent the upper vertebra;

a lower load bearing member for being implanted in the intervertebral space within the intact, natural annulus adjacent the lower vertebra;

a polyetheretherketone (PEEK) material of both the upper load bearing member and the lower load bearing member so that the load bearing members are of matching material;

PEEK outer bearing surfaces of the matched PEEK load bearing members having a smooth configuration for the entire extent thereof so as to lack any protrusions projecting outwardly therefrom for non-invasive sliding engagement with the corresponding intact, natural end plates; and

PEEK inner bearing surfaces of the matched PEEK load bearing members each having an arcuate configuration that cooperate to engage each other and allow for polyaxial rotation and sliding of the matched PEEK load bearing members relative to each other so that there are multiple PEEK outer bearing interfaces and a PEEK-on-PEEK inner bearing interface with the PEEK outer surfaces of the load bearing members forming the multiple PEEK outer bearing interfaces and the PEEK inner surfaces of the load bearing members forming the PEEK-on-



PEEK inner bearing interface to allow for differential shifting of the different PEEK bearing interfaces optimizing wear resistance thereof and cyclical load capacity provided thereby.

43. (Previously presented) The nucleus implant device of claim 42 wherein the PEEK outer bearing surfaces comprise smooth, flat surfaces.

44. (Previously presented) The nucleus implant device of claim 42 wherein the arcuate inner bearing surfaces comprise a dome surface and a concave recessed surface for receiving the dome surface in engagement therewith with each engaging inner bearing surface being uninterrupted the entire extent thereof for smooth, continuous bearing engagement therebetween.

45. (Previously presented) The nucleus implant device of claim 42 wherein at least one of the load bearing members has a post configured to be engaged by a tool for implanting at least the one load bearing member in the intervertebral space.

46. (Previously presented) The nucleus implant device of claim 45 wherein both load bearing members include posts for a tool, and the arcuate inner bearing surfaces comprise a dome surface and a concave recessed surface sized such that with the dome surface engaged in the concave recessed surface, the posts aligned with each other, and plate bodies of the load bearing members generally extending in parallel to each other, a predetermined gap spacing is provided between free ends of the aligned posts to avoid significant interference with the relative movement between the load bearing members at the inner bearing interface.

47. (Previously presented) The nucleus implant device of claim 42 wherein the load bearing members each have an elongated configuration with opposite narrow ends and long sides extending between the narrow ends allowing an incision in the annulus to be kept to a minimum

size with the load bearing members inserted therethrough with the narrow ends leading the members through the incision.

48. (Previously presented) The nucleus implant device of claim 42 wherein the load bearing members include bodies that are entirely of the PEEK material including the bearing surfaces thereof less any radio opaque markers included in the PEEK bodies.

49. (Withdrawn) A method of replacing a nucleus of a spinal disc, the method including:  
cutting an incision of a predetermined size in an annulus of the spinal disc;  
providing an implant device having top and bottom members;  
inserting the members of the device sequentially or together through the incision between top and bottom vertebrae;  
surrounding the members of the device with the annulus to hold the implant device between the vertebrae within the annulus ;  
engaging a convex inner surface of one of the implant members against a concave inner surface of the other implant member to provide for sliding and rotating relative movement between the implant members; and  
non-invasively engaging outer surfaces of the top and bottom members with end plates of adjacent top and bottom vertebrae for sliding thereagainst.

50. (Withdrawn) The method of claim 49 wherein the outer surfaces of the top and bottom members are engaged with the end plates, and the inner convex and concave surfaces are engaged with each other by forming the top and bottom member of polyetheretherketone, and non-invasively engaging polyetheretherketone outer surfaces of the implant members against the end plates, and engaging polyetheretherketone inner surfaces of the implant members against each other.

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51. (Withdrawn) The method of claim 49 wherein the members are inserted through the annulus incision by inserting the narrow ends of the member through the incision along an insertion direction and reorienting the members in the annulus so that the narrow ends are not aligned with the insertion direction.

52. (New) The device of claim 1, wherein the outer bearing surfaces are substantially race-track shaped for allowing the bearing members to fit within the natural annulus.

53. (New) The device of claim 1, wherein the narrow ends of the shells each have an arcuate configuration and the elongate sides extend parallel to one another between the narrow ends.

54. (New) The device of claim 1, wherein the smooth outer surfaces of the shells are entirely free of bone-engaging protrusions or surface roughening to promote sliding engagement of the bearing members with the end plates such that the nucleus device is allowed to move freely along the endplates within the annulus.